

Is It Malaria Pf/Pv Device
Detection Kit for Malarial Antigens, P. falciparum-specific pLDH and Pan malaria-specific pLDH/aldolase

EXPLANATION OF THE TEST

Is It Malaria Pf/Pv Device is a chromatographic immunoassay kit for rapid qualitative determination of malaria infection using blood specimen. Malarial antigens, LDH (lactate dehydrogenase) and aldolase, in blood sample are allowed to react with the anti-LDH and anti-aldolase monoclonal antibody-coupled gold conjugate followed by reaction with anti-LDH or anti-aldolase monoclonal antibody in the test lines. When the blood sample is infected with malaria, a visible line appears in the test region on the membrane. Is It Malaria Pf/Pv Device can also discriminate between P. falciparum and P. vivax (Pan).

PROPERTIES

Is It Malaria Pf/Pv Device can detect malarial antigens so that the kit is suitable for the diagnosis of all 4 kinds of malaria, including P. falciparum, P. vivax, P. malariae and P. ovale.

MATERIALS PROVIDED

Is It Malaria Pf/Pv Device kit contains the following items:

1. Is It Malaria Pf/Pv Device
2. Sample Applicator
3. Assay Solution
4. Instruction manual

PRECAUTIONS

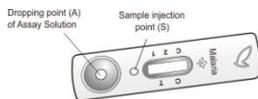
1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date.
3. For in vitro diagnostic use only.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose all the samples and kits properly after test, in accordance with GLP.
6. Do not pipette reagent or blood by mouth.
7. Do not interpret results after 30 minutes.

SPECIMEN COLLECTION AND STORAGE

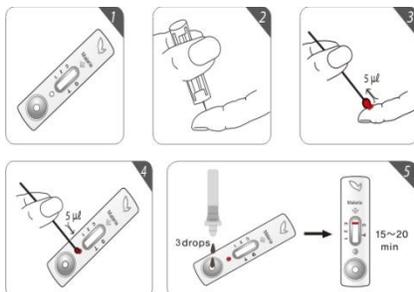
1. The test should be performed with freshly collected human blood collected from the fingertip or by venipuncture using sample tube containing anticoagulant.
2. For short term storage please keep the specimen at 2-8°C, for long term storage please keep the sample below -20°C.

TEST PROCEDURE

1. Take a device from the pouch.
2. Clean the fingertip with the alcohol swab (not provided in this kit), and dry completely. Prick the fingertip with a Single Use Lancet. [Caution: Do not reuse the lancet !!]
3. Collect 5 µl of blood using the Sample Applicator.
4. Load the 5 µl of blood into the sample injection point (S) of the test device.
5. Add 3 drops of Assay Solution into the dropping point (A) of the test device.



6. Wait for the reaction for 15~20 minutes.
7. Interpret the result.

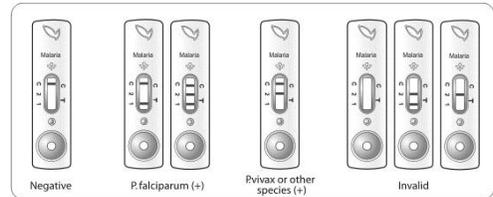


STORAGE & EXPIRATION

1. Is It Malaria Pf/Pv Device kit should be stored between 2 to 30°C (36-86°F).
2. Expiration date of this kit is 18 months after its manufacture date.

INTERPRETATION OF THE RESULTS

- **NEGATIVE:** Only the control band is visible. Negative result indicates that there is no malaria infection in the sample.
- **POSITIVE:** Along with the control band, if the T1 or the T1+T2 band appear together, the blood sample is infected with P.falciparum. If only the T2 band appears, the blood sample is infected by P. vivax (usual) or P.malariae/P.ovale (rare).
- **INVALID:** If control band does not appear, the test is invalid. In this case, please repeat the test, following the test procedure exactly.



LIMITATIONS OF THE TEST

Is It Malaria Pf/Pv Device is designed as a primary screening test for malaria infection. This kit can provide fast and easy way to get a result, but does not completely exclude the possibility of false positive or false negative result caused by various factors. So refer to the result of this kit, please make a final decision with clinical manifestation, other test results and doctor's view collectively.

PERFORMANCE CHARACTERISTICS

Detection limit

Detection limit of Is It Malaria Pf/Pv Device is approx. 50 parasites/ul of the blood.

Microscopy	Is It Malaria Pf/Pv	
Parasites/ul*	Test No.	Results**
10-20	10	8:2
21-50	10	1:9
51-100	10	0:10
101-200	10	0:10
201-400	10	0:10

* P. falciparum culture

** No. of Negatives : No. of Positives

In 50 healthy patient samples, all tests performed on Is It Malaria Ag were reported as negative. Sensitivity and Specificity were ~100%

REFERENCES

1. World Health Organization-Geneva (2000) New perspectives malaria diagnosis.
2. Perlmann, P. and Troye-Blomberg, M. 2002. Malaria parasites and disease. Malaria Immunology.
3. Malcolm, J. G., et al., 2002. Genome sequence of the human malaria parasite Plasmodium falciparum. Nature. 419: 498-511
4. Warhurst, D.C., and J. E. Williams. 1996. Laboratory diagnosis of malaria. J. Clin. Pathol. 49: 533-538

Disclaimer:

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and / or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning:

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

Manufactured by:



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